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Review of Assisted Reproductive Technology and Prenatal Torts in Pennsylvania, A

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A Review of Assisted Reproductive Technology and Prenatal Torts in Pennsylvania

Tiffany Jenca *

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I. INTRODUCTION

Each year, tens of thousands of Americans turn to assisted reproductive technology (“ART”) for help in achieving their dreams of parenthood.¹ As reported by the Centers for Disease Control, the proportion of live births to total attempted ART cycles represents the “success rate” of ART operations,² and these success rates are closely monitored in accordance with federal law.³

Unfortunately, in some cases where donated tissue is used in ART procedures, a genetic defect may be transmitted that results in the birth of a child suffering from a severe and incurable disease.⁴ For these families, any bare mathematical concept of “suc-

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1. Centers for Disease Control and Prevention, *2010 Assisted Reproductive Technology Fertility Clinic Success Rates Report*, CDC – ART REPORT – DIVISION OF REPRODUCTIVE HEALTH 21, http://www.cdc.gov/art/ART2010/PDFs/ART_2010_Clinic_Report-Full.pdf (last updated Dec. 20, 2012).

2. *Id.* at 6.

3. See Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a (2006).

4. See *Johnson v. Superior Court of L.A. Cnty.*, 124 Cal. Rptr. 2d 650, 653 (Cal. Ct. App. 2002) (involving a child diagnosed with autosomal polycystic kidney disease, which was inherited from a sperm donor with a history of same); *Paretta v. Med. Offices for Hu-*

cess" may be a woefully inadequate representation of their ART experience. Nevertheless, there is no federal regulation requiring screening or testing for genetic defects in donated reproductive material.⁵ As a result, state courts are left struggling to apply existing state statutes and traditional tort theory to a wholly new subset of medical malpractice claims.⁶

This article will begin by providing an overview of ART procedures and the sparse federal regulations applicable to donated reproductive tissue. Then, the discussion will turn to the legal environment in Pennsylvania, which demonstrates that existing state laws may be unprepared to handle ART-related claims. Specifically, this article will review state tort precedent, current legislation barring particular tort claims,⁷ and the unintended effect these laws may have on ART-related actions. Finally, this article will suggest three changes in Pennsylvania law that would clarify tort concepts and permit an opportunity for meaningful recovery in ART-related cases involving donated reproductive material. These changes include clarification of existing statutory language, modification of tort laws regarding the measure of damages in prenatal tort actions, and implementation of regulations that establish donor screening requirements for genetic defects in reproductive material.

II. BACKGROUND

The phrase "Assisted Reproductive Technology," ("ART") is used to describe "all treatments or procedures which include the handling of human oocytes⁸ or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies."⁹ Stated more simply, ART includes "all fertility treatments in which both eggs and sperm are handled."¹⁰ This definition is intended to exclude procedures involving only one source of reproductive material, such

man Reprod., 760 N.Y.S.2d 639 (N.Y. Sup. Ct. 2002) (involving a child suffering from cystic fibrosis).

5. See *infra* discussion in Part II.

6. See *infra* discussion in Part III.

7. 42 PA. CONS. STAT. ANN. § 8305 (West 2007).

8. "The female reproductive cell, also called an egg." Centers for Disease Control and Prevention, *supra* note 1, at 477.

9. Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-7(1) (2006).

10. Centers for Disease Control and Prevention, *supra* note 1, at 3.

as artificial insemination.¹¹ ART procedures involve “surgically removing eggs from a woman’s ovaries, combining them with sperm in the laboratory, and returning them to the woman’s body or donating them to another woman.”¹² The most popular form of ART is in vitro fertilization.¹³

In 1992, Congress sought to establish a uniform system of certification and reporting for the “success rates” of ART, so it enacted the Fertility Clinic Success Rate and Certification Act of 1992 (“FCSRCA”).¹⁴ This act requires all clinics that perform ART procedures to report annual data to the Centers for Disease Control (“CDC”).¹⁵ The CDC is then responsible for compiling this data into an annual report detailing the success rates of each reporting clinic.¹⁶

The most recent CDC Assisted Reproductive Technology report was published in 2012 and reflects the clinic data reported for calendar year 2010.¹⁷ This report details the procedures of 443 reporting clinics throughout the United States, and highlights a total of 147,260 ART cycles performed in 2010.¹⁸ According to the report, 47,090 live births resulted from the 2010 ART cycles,¹⁹ which is more than one and a half times the number of live births from ART in 2001.²⁰ Notably, while the total number of live births increased over 60% from 2001 to 2010,²¹ the total number of ART cycles performed increased only 37% during the same time peri-

11. *Id.*

12. *Id.*

13. *Id.*

14. 42 U.S.C. § 263a.

15. *Id.* § 263a-1.

16. *Id.* § 263a-5. Under the FCSRCA, the CDC was also required to “develop a model program for the certification of embryo laboratories, to be carried out voluntarily by interested states.” Implementation of the Fertility Clinic Success Rate and Certification Act of 1992 – A Model Program for the Certification of Embryo Laboratories; Notice, 64 Fed. Reg. 39374 (July 21, 1999). However, the resulting model act does not require donor screening for genetic disease, nor genetic testing for donated reproductive material. *Id.*

17. Centers for Disease Control and Prevention, *supra* note 1, at 4-5.

18. *Id.* at 5.

19. Centers for Disease Control and Prevention, *2010 Assisted Reproductive Technology National Summary Report*, CDC – ART REPORT – DIVISION OF REPRODUCTIVE HEALTH 52, http://www.cdc.gov/art/ART2010/PDFs/ART_2010_National_Summary_Report.pdf (last updated Jan. 30, 2013). A total of 61,564 infants resulted from the 47,090 live births attributed to ART in 2010. *Id.*

20. *Id.* The CDC reports 29,344 live births from ART in 2001, which resulted in 40,687 infants. *Id.*

21. *Id.* CDC data shows 29,344 live births from ART cycles conducted in 2001 and 47,090 live births from ART cycles conducted in 2010. *Id.*

od.²² Thus, it appears as though the increase in the total number of births is not due merely to an increase in ART cycles, but may also be attributed to scientific advancements.

However, despite the reporting requirements of the FCSRCA, the legislation did not mandate quality standards for ART procedures, nor did it provide any requirements specific to donated reproductive material.²³ In fact, this aspect of ART went largely unregulated until the Food and Drug Administration ("FDA") enacted provisions of the Human Tissue Regulations that pertain specifically to donor eligibility, including donor screening and testing.²⁴ Under the FDA's Human Tissue Regulations, establishments that engage in the "manufacture of human cells, tissues and cellular and tissue-based products"²⁵ are required to follow specific instructions for the "recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor."²⁶

To make clear that these provisions apply to the components of ART, the Human Tissue Regulations define "[h]uman cells, tissues, or cellular or tissue-based products (HCT/Ps)" as "articles consisting of human cells or tissues," which "include, but are not limited to . . . semen or other reproductive tissue."²⁷ Also, the regulations separately define the term "transfer" to mean "the placement of human reproductive cells or tissues into a human recipient."²⁸

With regard to donated HCT/P material, the FDA requires a donor-eligibility determination²⁹ based on individual donor screening and testing.³⁰ The screening regulations specifically mandate that the donor's "relevant medical records"³¹ are reviewed for "risk factors for, and clinical evidence of, relevant communicable dis-

22. *Id.* CDC data shows 107,587 total ART cycles in 2001 and 147,260 total ART cycles in 2010. *Id.*

23. Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-7(1) (2006).

24. FDA Human Tissue Regulations, 21 C.F.R. § 1271.45 (2005).

25. *Id.* § 1271.3(b).

26. *Id.* § 1271.3(e).

27. *Id.* § 1271.3(d).

28. *Id.* § 1271.3(g).

29. *Id.* § 1271.45(b).

30. *Id.* § 1271.50. Note, however, that neither the screening nor testing requirements of this section apply to material donated for autologous use or material donated by a sexually intimate partner. *Id.* § 1271.90.

31. *Id.* § 1271.3(s) (defining "relevant medical records" as a "collection of documents that includes a current donor medical history interview" as well as available laboratory test results, medical records and other information pertaining to communicable diseases).

ease agents and diseases,”³² which include viruses such as HIV, Hepatitis B and Hepatitis C.³³ For donated reproductive material, such as the semen and oocytes that may be used in ART procedures, the regulations add screening requirements for “relevant communicable diseases of the genitourinary tract, such as chlamydia and gonorrhea.”³⁴ Similarly, the testing regulations require that donor specimens are tested for “evidence of infection due to relevant communicable disease agents.”³⁵

However, just as ART provides society with new and inventive ways to overcome infertility, it also provides unique risks that are relatively new to the legal landscape. For example, donated reproductive material is unique from other donated tissue because its purpose is to create human life rather than provide therapeutic treatment for the recipient. Thus, donated reproductive tissue often plays an integral role in determining the genetic makeup of infants conceived through ART, and the FDA regulations regarding communicable disease agents stop short of establishing any standards for the identification of genetic defects in donors or donated material.

There are instances in which failed screening, testing or counseling practices in an ART procedure have resulted in the birth of an infant afflicted with serious illness or deformity.³⁶ In these instances, courts have been faced with relatively new tort concepts such as wrongful birth and wrongful life.³⁷ Both wrongful birth and wrongful life are medical-malpractice actions,³⁸ but the important distinction between them is the party alleging injury. In a wrongful birth case, “the parents of an unhealthy child born following negligent genetic counseling or negligent failure to diagnose a fetal defect or disease” institute an action on the basis that “they were wrongfully deprived of the ability to avoid or terminate a pregnancy to prevent the birth of a child with the defect or disease.”³⁹ However, in a wrongful life action, the unhealthy child resulting from “a negligently performed sterilization . . . or negli-

32. *Id.* § 1271.75(a).

33. *Id.*

34. *Id.* § 1271.75(c).

35. *Id.* § 1271.85.

36. See *Johnson v. Superior Court of L.A. Cnty.*, 124 Cal. Rptr. 2d 650 (Cal. Ct. App. 2002); *Paretta v. Med. Offices for Human Reprod.*, 760 N.Y.S.2d 639 (N.Y. Sup. Ct. 2002).

37. *Schirmer v. Mount Auburn Obstetrics & Gynecologic Assocs., Inc.*, 844 N.E.2d 1160, 1164 (Ohio 2006) (defining wrongful birth and wrongful life actions in Ohio).

38. *Id.*

39. *Id.*

gent genetic counseling or testing argues that he or she has been damaged by being born at all.⁴⁰ The former cause of action is permitted in some jurisdictions, but the vast majority of jurisdictions refuse to recognize a cause of action for wrongful life.⁴¹

In late 2012, the Society for Assisted Reproductive Technology (“SART”) attempted to prevent these situations and fill the gap in FDA regulations by publishing the “Recommendations for evaluation of potential sperm, oocyte and embryo donation.”⁴² SART is the “primary organization of professionals dedicated to the practice of assisted reproductive technologies . . . in the United States,”⁴³ and the organization works closely with the CDC in developing the annual report required under the FCSRCA.⁴⁴ More than 375 ART clinics in the United States are members of SART,⁴⁵ and it is a requirement of membership that each facility adhere to all SART guidelines.⁴⁶ Additionally, SART requires its members to obtain laboratory accreditation through the College of American Pathologists (“CAP”), or The Joint Commission (“JCHOA”).⁴⁷

The guidelines titled “Recommendations for gamete and embryo donation: a committee opinion” – published in October 2012 – set forth “recommendations for evaluation of potential sperm, oocyte and embryo donors,”⁴⁸ which in many instances are “more stringent than the FDA minimum requirements.”⁴⁹ For example, these guidelines recommend particular tests for oocyte recipients and their partners.⁵⁰ The guidelines also recommend a list of factors to be considered for the selection, screening and testing of potential

40. *Id.*

41. *Id.*

42. Am. Soc’y for Reprod. Med. and Soc’y for Assisted Reprod. Tech., *Recommendations for gamete and embryo donation: a committee opinion*, ASRM GUIDELINES FOR PRACTICE (Oct. 16, 2012), [http://www.sart.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/2008_Guidelines_for_gamete\(1\).pdf](http://www.sart.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/2008_Guidelines_for_gamete(1).pdf) (last visited January 18, 2013).

43. SART: *What is SART?*, SART.ORG, http://www.sart.org/What_is_SART/ (last visited January 18, 2013).

44. Centers for Disease Control and Prevention, *supra* note 1, at iv.

45. SART: *What is SART?*, SART.ORG, http://www.sart.org/What_is_SART/ (last visited January 18, 2013). This equates to more than 85% of the ART clinics in the country. *Id.*

46. *Requirements for SART Membership*, SART.ORG, http://www.sart.org/uploadedFiles/Affiliates/SART/Members/Membership%20Requirements%2007_08.pdf (last visited Jan. 18, 2013).

47. *Id.*

48. Am. Soc’y for Reprod. Med. and Soc’y for Assisted Reprod. Tech., *supra* note 42, at 1.

49. *Id.*

50. *Id.* at 8.

oocyte donors.⁵¹ Specifically, when selecting donors SART recommends that “the donor should undergo appropriate genetic evaluation based on history, in accordance with ethnic background and current guidelines,” “cystic fibrosis testing should be performed on all donors,” and “consideration should be given to fragile X testing on donors, but is not required.”⁵² Additionally, the guidelines for screening a potential donor recommend that “[d]onors should be healthy and give no history to suggest hereditary disease.”⁵³ Similar guidelines apply for embryo donation.⁵⁴

Unfortunately, despite the thorough recommendations provided by SART, there is nothing to suggest that ART clinics are required to participate in SART in the first instance. Moreover, although SART may be entitled to rescind the membership of any non-compliant clinic, the guidelines themselves do not provide redress for a family injured by the actions or omissions of the non-compliant facility. In fact, SART give a nod of deference to the decisions of individual facility physicians by expressly stating that the guidelines are “not intended to be a protocol to be applied in all situations, and cannot substitute for the individual judgment of the treating physicians.”⁵⁵ As a result, tort concepts remain the only avenue through which families affected by a non-member or non-compliant ART clinic might seek relief.

III. ANALYSIS

A. *State of the Law in Pennsylvania*

The most recent CDC Assisted Reproductive Technology report documents nineteen ART facilities in Pennsylvania, which attempted a total of 4,424 ART cycles in 2010.⁵⁶ Of the nineteen facilities operating in Pennsylvania, fifteen are identified as members of SART, and the majority maintain CAP or JCHOA laboratory accreditation.⁵⁷ Fortunately, a review of Pennsylvania authority suggests the Commonwealth has not yet faced a case regarding a child disabled by genetic defect as a result of absent or

51. *Id.*

52. *Id.* at 9.

53. *Id.*

54. *Id.* at 12.

55. *ASRM Guidelines for Practice*, SART.ORG, <http://www.sart.org/guidelines/> (last visited January 18, 2013).

56. Centers for Disease Control and Prevention, *supra* note 1, at 357-75.

57. *Id.*

negligent genetic screening, testing or counseling in an ART procedure. Nevertheless, Pennsylvania's legal landscape is framed such that ART patients and their children will have little, if any, recourse should such a case arise.⁵⁸

The Supreme Court of Pennsylvania first introduced the Commonwealth to the concept of prenatal torts⁵⁹ in the 1981 case of *Speck v. Finegold*.⁶⁰ In this case, Frank and Dorothy Speck were parents to two children suffering from an inherited defect causing neurofibromatosis.⁶¹ "For genetic and economic reasons," the Specks decided against having any additional children and engaged a urologist to perform a vasectomy upon Mr. Speck.⁶² When Mrs. Speck subsequently became pregnant, the couple engaged another physician to terminate Mrs. Speck's pregnancy.⁶³ Despite these efforts to avoid, and then to terminate, this pregnancy, Mrs. Speck gave birth to a third child with neurofibromatosis.⁶⁴

In evaluating the remedies available to the Speck family, the court concluded it would "approve a cause of action brought by the parents of an unplanned, unwanted, genetically defective child for the birth of that child."⁶⁵ The court suggested to hold otherwise would frustrate "the fundamental policies of tort law in the Commonwealth: to compensate the victim, deter negligence, and encourage due care,"⁶⁶ and determined that foreseeable damages for mental distress were permissible in addition to the "usual common-law principles of damages."⁶⁷

The court also approved "a cause of action brought by an unplanned, unwanted, genetically defective child for the child's

58. See, e.g., *Jenkins v. Hosp. of the Med. Coll. of Pa.*, 634 A.2d 1099, 1105 (Pa. 1993) (noting that state statute both complicates Pennsylvania tort law and eliminates a cause of action available to parents of a child suffering from genetic disease); *Ellis v. Sherman*, 515 A.2d 1327, 1329-30 (Pa. 1986) (holding no cause of action available on behalf of minor child suffering from genetic disease).

59. *Schirmer v. Mount Auburn Obstetrics & Gynecologic Assocs., Inc.*, 844 N.E.2d 1160, 1164 (Ohio 2006) (illustrating typical categories of prenatal torts, including wrongful pregnancy, wrongful birth and wrongful life).

60. 439 A.2d 110 (Pa. 1981).

61. *Id.* at 112.

62. *Id.* at 113.

63. *Id.*

64. *Id.*

65. *Id.* The Supreme Court of Pennsylvania later clarified that it considered this action to be a claim sounding in medical malpractice, rather than styled as wrongful birth or wrongful life. *Jenkins v. Hosp. of the Med. Coll. of Pa.*, 634 A.2d 1099, 1105 (Pa. 1993).

66. *Speck*, 439 A.2d at 114.

67. *Id.*

birth,”⁶⁸ and expressly rejected the view of other jurisdictions that such actions should be barred due to the impossible task of calculating the value of existence.⁶⁹ Rather, the court commented that jurisdictions “holding such views are apparently able to overlook what is plain to see: that – in cases such as this – a diseased plaintiff exists and, . . . would not exist at all but for the negligence of the defendants.”⁷⁰

One year later, the Supreme Court of Pennsylvania examined the ruling in *Speck* with regard to damages for the birth of an unplanned, unwanted but healthy child.⁷¹ In *Mason v. Western Pennsylvania Hospital*, a divided court held that when an improper sterilization procedure results in the birth of a healthy child, the parents are “entitled to recover all medical expenses and lost wages related to pre-natal care, delivery, and post-natal care, as well as compensation for pain and suffering incurred during the pre-natal through post-natal periods.”⁷² However, these parents are not entitled to damages for “emotional distress and the expenses of raising the child until the ‘age of maturity,’” which would otherwise be available under *Speck* if the child at issue were diseased or disabled.⁷³

By 1986, the Supreme Court of Pennsylvania began to depart from the broad protections afforded to prenatal tort claims under *Speck*.⁷⁴ In *Ellis v. Sherman*, for example, the court examined “whether a child born with a debilitating disease may bring an action against medical practitioners who fail to advise his parents of the probability that he will be born with such a disease, thus foreclosing parental opportunity to avoid the pregnancy and to prevent his being born.”⁷⁵ At the outset, the *Ellis* case differed slightly from *Speck* because the plaintiffs did not allege a negligent performance of sterilization procedures. Rather, the plaintiffs in *Ellis* claimed family doctors failed to advise them before or during their pregnancy that Mr. Ellis carried the hereditary dis-

68. *Id.* at 113. The Supreme Court of Pennsylvania later clarified that it considered this action to be the definition of wrongful birth in the Commonwealth until legislative intervention in 1988. *Jenkins*, 634 A.2d at 1105.

69. *Speck*, 439 A.2d at 115.

70. *Id.*

71. *Mason v. W. Pa. Hosp.*, 453 A.2d 974, 976 (Pa. 1982).

72. *Id.*

73. *Id.*

74. *Ellis v. Sherman*, 515 A.2d 1327 (Pa. 1986).

75. *Id.* at 1328.

ease known as neurofibromatosis.⁷⁶ Unfortunately, the disease was passed on to the Ellis' child, which resulted in "severe mental retardation, physical and motor development delay, deformity, and seizures."⁷⁷

However, where the court once saw a diseased plaintiff deserving of redress,⁷⁸ they now saw a child-plaintiff without a cause of action for the "alleged" injury of his birth.⁷⁹ Indeed, the court subscribed to the "hyper-scholastic rationale"⁸⁰ rejected in *Speck* by holding the "assertion that the child has been injured by its existence as too speculative" for determination.⁸¹ More specifically, the court applied the benefit rule,⁸² under which "special benefits" conferred to the plaintiff by tortious conduct offset the harm caused by the tortious conduct.⁸³ Because the court could not "say how the child's pain and suffering will compare to the benefits of its life,"⁸⁴ it could not be determined that "its life constitutes an injury."⁸⁵

While this rationale alone has been sufficient to dispose of the infant's claims in many jurisdictions,⁸⁶ the *Ellis* court also adopted a second theory, which relied on the legal definition of "injury."⁸⁷ In fact, the court devoted nearly one-third of its opinion to a discussion focused on the distinction between tortious interference and traditional human pro-creation.⁸⁸ Though ultimately concluding that the plaintiff in *Ellis* lacked an injury because the harm was a result of the "plaintiff's genetic constitution"⁸⁹ and was not "inflicted upon the plaintiff"⁹⁰ by any person, the court left open the possibility that "this condition presumably would constitute a legal injury if it had been inflicted [upon the plaintiff] by some negligent or intentional act of another."⁹¹ Finally, the court reit-

76. *Id.*

77. *Id.*

78. *See, e.g., Speck v. Finegold*, 439 A.2d 110, 115 (Pa. 1981).

79. *Ellis*, 515 A.2d at 1328.

80. *See Speck*, 439 A.2d at 115.

81. *Ellis*, 515 A.2d at 1329.

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *See, e.g., Paretta v. Med. Offices for Human Reprod.*, 760 N.Y.S.2d 639, 644 (N.Y. Sup. Ct. 2002) (discussing lack of cognizable injury).

87. *Ellis*, 515 A.2d at 1329.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

erated its holding in language prophetically suited for the advent of ART: "When life comes into being unimpeded by outside forces and is formed solely by its own internal controls, that life cannot be said to constitute an injury."⁹² Thus, it seems that the *Ellis* court successfully limited the scope of a child's claim under *Speck* but retained a cause of action for situations where the plaintiff's genetic constitution is man-made and assembled externally, as is the case with most ART procedures.

Also, in *Ellis*, the Supreme Court of Pennsylvania expressly preserved the parents' right to relief under *Speck*.⁹³ Before disposing of the case, the court noted that the "parents' right of recovery is not at issue,"⁹⁴ and concluded the *Ellis* family would be able to recover for mental anguish as well as expenses related to the birth and care of their child if successful in establishing their claim.⁹⁵

Two years later, the Pennsylvania legislature eliminated any such gaps existing in the *Ellis* decision, and enacted a statutory prohibition on both wrongful birth and wrongful life claims.⁹⁶ The statute provides, in relevant part:

(a) Wrongful birth. – There shall be no cause of action or award of damages on behalf of any person based on a claim that, but for an act or omission of the defendant, a person once conceived would not or should not have been born

(b) Wrongful life. – There shall be no cause of action on behalf of any person based on a claim of that person, that, but for an act or omission of the defendant, the person would not have been conceived or, once conceived, would or should have been aborted.

(c) Conception. – A person shall be deemed to be conceived at the moment of fertilization.⁹⁷

92. *Id.*

93. *Id.* at 1330.

94. *Id.*

95. *Id.*

96. 42 PA. CONS. STAT. ANN. § 8305 (West 2007). The Pennsylvania Superior Court recently held this statute unconstitutional on procedural grounds. *Sernovitz v. Dershaw*, 57 A.3d 1254 (Pa. Super. 2012) (holding section 8305 is unconstitutional under the single-subject rule of Article III, Section 3 of the Pennsylvania Constitution); *contra* *Dansby v. Thomas Jefferson Univ. Hosp.*, 623 A.2d 816, 818 (Pa. Super. 1993) (upholding section 8305 against substantive constitutional challenges on the basis that "lawfully enacted legislation enjoys a presumption of constitutionality")

97. 42 PA. CONS. STAT. ANN. § 8305.

Almost immediately thereafter, the Pennsylvania judiciary struggled with the application of the new statute.⁹⁸ For example, in the 1989 case of *Hatter v. Landsberg*, the Superior Court of Pennsylvania evaluated a claim brought by parents of a healthy child, who was conceived and born after a negligently performed tubal ligation.⁹⁹ The Hatters sought damages for "pre and post-natal expenses, pain and suffering, and emotional distress,"¹⁰⁰ stemming from the unwanted and unplanned pregnancy. Meanwhile, the defendant physician argued that section 8305 barred the Hatters' claim by abolishing any cause of action for wrongful birth or wrongful life.¹⁰¹ At the outset, the court identified that the wrongful life provision was not at issue, because there was no action brought on behalf of the child.¹⁰² However, the court deemed the statutory language of the wrongful birth provision unclear, and relied on legislative history to determine whether the statute barred claims such as those presented by the Hatters.¹⁰³

Citing to legislative debates regarding section 8305, the court introduced Pennsylvania to a third type of prenatal tort: wrongful conception.¹⁰⁴ Under *Hatter*, wrongful conception is defined as "an action seeking damages for negligence occurring prior to conception,"¹⁰⁵ and these actions may include claims against physicians for "so-called botched or fully negligent sterilization."¹⁰⁶ Additionally, upon review of the legislative history, the court concluded that the legislative intent of section 8305 was to eliminate "suits brought by children or their parents in an effort to recover damages for failure to abort a child or negligently aborting a child,"¹⁰⁷ so as to "prevent law suits leading to eugenic abortions of deformed or unwanted children."¹⁰⁸ The court directly concluded section 8305 was "not intended to bar cases of 'wrongful conception,'"¹⁰⁹ and this new terminology allowed the court to dispose of the case in a manner wholly consistent with the *Mason* precedent.

98. *Hatter v. Landsberg*, 563 A.2d 146 (Pa. Super. 1989).

99. *Id.* at 148.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.* at 150.

104. *Id.* at 149.

105. *Id.*

106. *Id.*

107. *Id.* at 150.

108. *Id.*

109. *Id.*

Four years later, the Supreme Court of Pennsylvania used the case of *Jenkins v. Hospital of Medical College of Pennsylvania* to express its disapproval of the prenatal tort statute.¹¹⁰ Through a review of its precedent in *Ellis, Mason and Speck*, the court suggested that the legislation confuses, rather than clarifies, wrongful birth and wrongful life actions.¹¹¹

First, the court employed its holding in *Ellis* to define “wrongful birth” as “a lawsuit brought on behalf of an infant who was born . . . deformed and diseased as the result of the failure of physicians to inform its parents of the possibility of diseased birth.”¹¹² Generally, the court agreed with the legislature in that there is no recognized cause of action available on behalf of the child.¹¹³ However, contrary to the *Ellis* definition, claims brought on behalf of the child are termed “wrongful life” actions under section 8305.¹¹⁴

Next, the court addressed the statutory definition of “wrongful birth,”¹¹⁵ in contrast to existing tort precedent.¹¹⁶ The court maintained that, until the enactment of section 8305, “lawsuits brought by parents in these cases for their own alleged injuries were not referred to as ‘wrongful birth’ actions, but merely as medical malpractice actions.”¹¹⁷ Thus, the court concluded the statute “introduces confusion” and eliminates a cause of action afforded to parents in tort cases for over a decade.¹¹⁸

B. Changing the Legal Landscape in Pennsylvania to Afford ART Patients Appropriate Relief for Medical Malpractice Claims

The current state of Pennsylvania law creates significant challenges for ART patients seeking recovery for medical malpractice. Consider, for example, the following hypothetical:¹¹⁹ Mr. and Mrs. Parent (“Parents”) suffered from infertility and, at the recommendation of a physician, agreed to undergo in vitro fertilization pro-

110. 634 A.2d 1099, 1105 (Pa. 1993).

111. *Id.*

112. *Id.*

113. *Id.*

114. 42 PA. CONS. STAT. ANN. § 8305(b) (West 2007).

115. *Jenkins*, 634 A.2d at 1105.

116. *Id.*

117. *Id.*

118. *Id.*

119. The facts of this hypothetical are actually those from the case of *Paretta v. Medical Offices for Human Reproduction*, 760 N.Y.S.2d 639, 641-42 (N.Y. Sup. Ct. 2002).

cedures using an ovum donor.¹²⁰ The Parents were given very specific information about a potential ovum donor, including her religious affiliation, sexual orientation, height, eye color, skin tone and facial structure.¹²¹ Allegedly, the fertility clinic also advised the Parents that the donor did not have a history of mental illness or genetic diseases.¹²² Pleased with this information, the Parents decided to pair the donor's eggs with Mr. Parent's sperm in hopes of a successful pregnancy.¹²³ However, despite the customary testing procedures at the clinic, neither the clinic nor the physician informed the Parents that their selected donor was a carrier of cystic fibrosis.¹²⁴ As a result of this omission, Mr. Parent was not tested to ascertain his status as a carrier of cystic fibrosis and the resulting child ("Baby") was born with the disease.¹²⁵ During her first few months of life, Baby was placed in intensive care, underwent multiple surgeries, and required a colostomy bag.¹²⁶ For the remainder of her life, it is expected Baby will require medication and hospital care.¹²⁷

In Pennsylvania, it is well-established there is no recourse available on behalf of Baby.¹²⁸ Mr. and Mrs. Parent, on the other hand, face two specific hurdles with regard to their potential claim. First, it must be determined whether there is a cause of action available to them in the Commonwealth of Pennsylvania. Then, if a cause of action exists, the scope of permissible damages must be defined.

After a review of Pennsylvania precedent and statutory restrictions, it is important to identify the specific allegations potential plaintiffs are likely to raise. For example, Mr. and Mrs. Parent may file a complaint based on negligent genetic testing and disclosure prior to the joining of Mr. Parent's sperm with the donor oocyte. This negligent conduct, occurring before conception, would fall within the scope of Pennsylvania's "wrongful concep-

120. *Id.* at 641.

121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.* at 642.

127. *Id.*

128. 42 PA. CONS. STAT. ANN. § 8305(b) (West 2007).

tion" action.¹²⁹ As such, their case should not be affected by section 8305.¹³⁰

However, the current state of the law in Pennsylvania requires strict discipline in the court's analysis of related, but chronologically distinct, ART claims. Suppose, for example, the parent-plaintiffs in our hypothetical situation opted to include an allegation of failure to disclose genetic information during the pregnancy period. Under current Pennsylvania law, this allegation may push our plaintiffs' claim into the realm of wrongful birth actions, and the prohibitions of section 8305 would terminate their claim.¹³¹ Likewise, Mr. and Mrs. Parent may have conceded their desire to abort the fetus had they been informed of the genetic defect. Again, this pushes the claim into the realm of wrongful birth actions, and it is barred under section 8305. Thus, for Parents' action to succeed, the allegations must be evaluated in chronological order, with a bright line separating pre-conception claims from post-conception claims.¹³²

Once it is established that the plaintiffs' wrongful conception action can proceed, we turn to the issue of damages. At current, the scope of damages permitted in a wrongful conception action is commensurate with the harm resulting from a negligent sterilization procedure.¹³³ However, the *Hatter* court did not define wrongful conception so narrowly,¹³⁴ and it is reasonable to believe the costs of tending to a child with serious genetic defects significantly

129. *Hatter v. Landsberg*, 563 A.2d 146, 149 (Pa. Super. 1989).

130. *Id.*

131. 42 PA. CONS. STAT. ANN. § 8305(a) (West 2007). This eliminates the prophylactic effect of tort law, as discussed in *Speck*, and may have the practical effect of incenting practitioners to delay genetic testing/counseling until the shield of section 8305 is firmly in place. *Speck v. Finegold*, 439 A.2d 110, 114 (Pa. 1981).

132. Under the facts of this case, the pre-conception claim stems from Parents' missed opportunity to select other gametes in the first instance due to negligence occurring before conception. This is Parents' wrongful conception claim, which should be recognized as a viable cause of action. That Parents, in hind-sight, acknowledge they may have aborted the pregnancy does not convert their pre-conception action based on a missed opportunity to select other gametes into a post-conception action based on a missed opportunity for abortion.

133. *Hatter*, 563 A.2d at 150; *Mason v. W. Pa. Hosp.*, 453 A.2d 974, 976 (Pa. 1982) (majority opinion) (limiting damages to the costs of "pre-natal care, delivery, and post-natal care, as well as compensation for pain and suffering incurred during the pre-natal through post-natal periods"). However, it has been argued that even the damages associated with a negligent sterilization procedure should not be so limited. *Mason*, 453 A.2d at 976.-79 (O'Brien, C.J., concurring and dissenting).

134. *Hatter*, 563 A.2d at 149 (defines wrongful conception as "an action seeking damages for negligence occurring prior to conception," but does not limit the action to cases involving only negligent sterilization).

surpass the “financial and emotional costs of raising a healthy child,” which are non-compensable in Pennsylvania.¹³⁵

In order to correct the inequities facing ART plaintiffs in Pennsylvania, there are three relatively simple courses of action recommended for the Commonwealth. First, to eliminate confusion and ambiguity regarding the naming conventions for prenatal torts, the Pennsylvania legislature might update section 8305 to include a provision defining the term “wrongful conception,”¹³⁶ and expressly preserving a cause of action for wrongful conception claims brought by any person other than the resulting child. For illustrative purposes, the new provision may read as follows: “(d) Wrongful conception. – Wrongful conception shall be defined as any action seeking damages for negligence occurring prior to conception, and no prior provision of this section shall be construed to extinguish a cause of action for wrongful conception.”

Though it does not subscribe to the term “wrongful conception,” Oklahoma statute provides an example of how “eugenic abortion” claims might be limited without barring other prenatal tort actions.¹³⁷ At the outset, the Oklahoma legislature makes clear “that the birth of a child does not constitute a legally recognizable injury and that it is contrary to public policy to award damages because of the birth of a child or for the rearing of that child.”¹³⁸ Thus, under Oklahoma statute, “in a wrongful life action or a wrongful birth action, no damages may be recovered for any condition that existed at the time of a child’s birth if the claim is that the defendant’s act or omission contributed to the mother’s not having obtained an abortion.”¹³⁹ However, the statute then clarifies that the prior sections – aimed at protecting public policy against abortion-based claims – “shall not preclude causes of action based on claims that, but for a wrongful act or omission, . . . disease, or disability of an individual prior to birth would have been prevented, cured, or ameliorated in a manner that preserved the health and life of the affected individual.”¹⁴⁰

Idaho has gone even further by adopting a statute that effectively delineates between “eugenic abortion” claims and other prenatal tort actions in general terms without the confusing prenatal

135. *Mason*, 453 A.2d at 976.

136. *Id.*

137. OKLA. STAT. ANN. tit. 63, § 1-741.12 (West 2012).

138. *Id.* § 1-741.12(A).

139. *Id.* § 1-741.12(C).

140. *Id.* § 1-741.12(D).

tort nomenclature.¹⁴¹ The statute simply mandates that “a cause of action shall not arise, and damages shall not be awarded, on behalf of any person, based on the claim that but for the act or omission of another, a person would not have been permitted to have been born alive but would have been aborted.”¹⁴² The statute then preserves potential causes of action for other prenatal torts in language substantially similar to that of Oklahoma.¹⁴³ However, there is a notable addition to the language of the Idaho statute in that it leaves open the opportunity for ART-based actions by stating that the “provisions of this section shall not preclude causes of action based on claims that, but for a wrongful act or omission, fertilization would not have occurred.”¹⁴⁴ These statutes demonstrate that it is possible to protect the public interest against eugenic abortions¹⁴⁵ without a complete bar to prenatal tort claims. The review of Pennsylvania law implies that the Commonwealth intends the same effect by statutorily barring wrongful birth and wrongful life claims, but judicially preserving the cause of action for wrongful conception. To clarify, and afford redress for ART-based claims that may arise in Pennsylvania, the legislature need only update statutory language to expressly provide protection for wrongful conception claims.

Next, tort reform is necessary in Pennsylvania with respect to damages permitted under a wrongful conception claim. Because ART-based wrongful conception actions may involve severe and incurable genetic defects, the Pennsylvania courts must allow flexibility in determining the scope of damages, which may require a departure from *Hatter*.¹⁴⁶ This is not to suggest all wrongful conception claims should entitle plaintiffs to extensive damages, but simply to acknowledge that varying classes of wrongful conception claims may require varied compensation.

141. IDAHO CODE ANN. § 5-334 (West 2012).

142. *Id.* § 5-334(1).

143. *Id.* § 5-334(2).

144. *Id.*

145. Despite the state interest in preventing eugenic abortions, the recent case of *Catlin v. Hamburg* affords a plaintiff alleging pre-conception negligence a greater opportunity for recovery if an abortion actually occurred. *Catlin v. Hamburg*, 56 A.3d 914, 924-25 (Pa. Super. 2012) (holding that, where plaintiff opted to abort a fetus with congenital abnormalities following a negligent sterilization procedure, the *Mason* limit on damages is not appropriate and victim must be compensated for “all that they suffer from the tort of another”).

146. *Paretta v. Med. Offices for Human Reprod.*, 760 N.Y.S.2d 639, 647 (N.Y. Sup. Ct. 2002) (indicating scope of damages for ART-based claims may include the cost of care and treatment for their child as well as punitive damages).

Finally, Pennsylvania should consider regulating facilities engaged in the manufacture of HTC/P products, as defined in the FDA Human Tissue Regulations.¹⁴⁷ Because the Human Tissue Regulations stop short of providing direction on genetic testing of reproductive material, it is recommended that the Commonwealth of Pennsylvania adopt a variation of these regulations enhanced to include key screening provisions for genetic defects. For clarity, the Commonwealth should adopt a variation of 21 C.F.R. § 1271.3, which defines the terminology used throughout the subsequent sections. Within this section, Pennsylvania should modify 21 C.F.R. § 1271.3(n) to include a mention of genetic defects, and revise 21 C.F.R. § 1271.3(s) to include “records or other information received from any source pertaining to genetic defects or diseases” in its definition of “relevant medical records.”¹⁴⁸ Also, the state regulation should adopt a variation of 21 C.F.R. § 1271.75, updated to include a provision requiring facilities to review donor medical records for information relating to genetic defects.¹⁴⁹ These simple regulatory enactments provide for the health and welfare of Pennsylvania’s current and future citizens,¹⁵⁰ establish a reasonable standard of care for genetic screening in the ART industry, and reduce the likelihood of ART-related wrongful conception claims without imposing incremental costs on the ART providers.¹⁵¹ Alternately, the Commonwealth might adopt the Human Tissue Regulations in their existing form for minimum requirements, and supplement the regulation by adopting the SART guidelines specific to donor selection, screening and testing.

IV. CONCLUSION

Assisted reproductive technology is a rapidly growing area of medical practice in the United States that often uses donated reproductive material to overcome patient infertility. However, there is scant regulation regarding donor screening or genetic testing of donated reproductive material. Thus, when cases arise in-

147. 21 C.F.R. § 1271.3 (2007).

148. *Id.* § 1271.3(s).

149. *Id.* § 1271.75(a).

150. Pennsylvania has stated its interest in safeguarding the health and wellbeing of its citizens through regulation of other medical facilities, such as blood banks. 35 P.S. § 6502 (2012).

151. 21 C.F.R. § 1271.3(s) (2007) (indicating establishments are already tasked with reviewing relevant records for other factors, which suggests there would be no incremental burden in reviewing them with an eye to genetic defects).

volving diseased children born of ART procedures, state courts are left piecing together existing state statutes and tort precedent to determine the relief, if any, available to ART plaintiffs.

Unfortunately, a review of Pennsylvania law demonstrates that the Commonwealth may be unprepared for the advent of ART-related claims. In fact, where *Ellis* left open the possibility for ART-related tort claims¹⁵² a state statute now bars all “wrongful life” and related “wrongful birth” actions.¹⁵³ In this environment, a prenatal tort claim – whether ART-related or otherwise – can exist only under the theory of “wrongful conception.” As such, *Hatter* limits recovery to the costs of pregnancy and delivery, which may be harshly inadequate compensation for a family raising a child suffering from an incurable genetic defect.

Overall, there are a few key concerns the Commonwealth should address to allow ART plaintiffs a fair opportunity for relief. First, it must be clear that ART-related claims of the type discussed herein are categorized as “wrongful conception” actions so as not to be automatically barred by section 8305. This can be accomplished by updating the current statutory language to delineate between the three categories of prenatal torts in Pennsylvania. Next, courts should be cognizant that ART-related tort claims may require a more flexible measurement of damages than is currently allowed under *Hatter*. Finally, to protect the welfare of its citizens and establish a clear standard of care regarding donated reproductive material, the Commonwealth should adopt regulatory provisions pertaining to mandatory donor screening for genetic disease. Together, these changes will offer much-needed clarification to the prenatal torts and transform Pennsylvania law such that it may protect both the interests of the Commonwealth and the interests of families relying on assisted reproductive technology.

152. *Ellis v. Sherman*, 515 A.2d 1327, 1329 (Pa. 1986).

153. 42 PA. CONS. STAT. ANN. § 8305 (West 2007).

